IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

No. 5:14-CV-468-F

SUSAN V. WILLIAMS, M.D., and R. BRUCE WILLIAMS, M.D.,	)	
Plaintiffs,	)	
v.	)	**ORDER**
ZIMMER US INC., ZIMMER INC., ZIMMER HOLDINGS, INC., ZIMMER SPINE, INC., JENNIFER CHEWNING, LOUISE YORK, PIONEER SURGICAL TECHNOLOGY, INC., RTI SURGICAL, INC., and HOWARD DYER,	)	
Defendants.	)	

This matter is before the court on Motions to Dismiss brought by Defendants Pioneer Surgical Technology ("Pioneer") and RTI Surgical [DE-27], Defendants Jennifer Chewning and Louise York [DE-39], and Defendant Howard Dyer [DE-54]. Also before the court are the plaintiffs' Motion to Remand for Lack of Original Federal Question Jurisdiction and of Exclusive Jurisdiction [DE-31] and Motion to Add Party Defendant [DE-43], and two motions by the defendants for leave to file supplemental opposition briefings [DE-50, 53]. The matters are ripe for ruling. For the reasons stated herein, the Motion to Remand [DE-31] is DENIED; the Motions to Dismiss [DE-27, -39, -54] are ALLOWED; the Motion to Add Party Defendant [DE-43] and the motions to file supplemental briefings [DE-50, -53] are DISMISSED AS MOOT.

I. PROCEDURAL AND FACTUAL BACKGROUND

This suit arises from allegations that the defendants "violated provisions of the federal Food Drug and Cosmetic Act [21 U.S.C. § 301 *et seq.*, the 'FDCA'], and more specifically the Medical Device Regulation Act [21 C.F.R. § 801 *et seq.*, the 'MDA'] by advising and/or discussing off-label use of a Zimmer product in conjunction with intra-operative placement of a medical device which had not been FDA-approved for that purpose." *See* Amended Complaint [DE-1-1] ¶ 1. Plaintiffs Susan and R. Bruce Williams initiated this action on July 23, 2014, by filing suit in state court. On August 15, 2014, Defendants Pioneer and RTI Surgical removed the action to this court. *See* Notice of Removal [DE-1]. The parties began filing the present motions a month later.

The allegations of the Amended Complaint, which the court must accept as true for purposes of the motions to dismiss, show the following: The Zimmer defendants, Pioneer, and RTI Surgical all manufacture "reconstructive orthopedic hardware and implants, including spinal implants," for use in orthopedic surgery. *See* Am. Compl. [DE-1-1] ¶¶ 36-37. Relevant to the present matter, Pioneer and RTI Surgical manufacture a 5.5 mm cobalt chromium rod that is used in orthopedic surgery to correct scoliosis and other conditions. *Id.* ¶ 39. The FDA has approved the 5.5 mm chrome rod for use in the thoracic and lumbar spine. *Id.* ¶ 40. Zimmer Clamps act as an interface "between orthopedic rods and the spinal anatomy during certain spinal surgeries." *Id.* ¶ 38.

Sometime before June 24, 2011, Plaintiff Susan Williams was in an automobile accident causing her severe neck pain that worsened over time. *Id.* ¶¶ 41-42.[1] After a consultation with Dr. Lloyd Albert Hey, Mrs. Williams agreed to undergo a procedure involving the Pioneer

[1] The Amended Complaint states that the accident happened in November 2011. *Id.* ¶ 42. However, given the other dates contained in the Amended Complaint, the stated year is most likely incorrect.

Posterior Cercivoc-Thoracic System ("PPCTS"). *See id.* ¶¶ 3, 44-48. The PPCTS had received "510(k) clearance by the Food and Drug Administration . . . in 2010 as a Class II medical device" based on its "substantial equivalence to FDA-approved, legally-marketed existing orthopedic devices." *Id.* ¶¶ 49-50. Ms. Williams's understanding was that the procedure would involve FDA- approved hardware "in a manner consistent with conventional use among spine surgeons." *Id.* ¶¶ 51-52.

On the evening of June 24, 2011, in his own garage, Dr. Hey used nonmedical tools purchased from a home improvement store to bend a 5.5 mm chrome rod into a "U" shape. *Id.* ¶¶ 57-58. While some of Pioneer's publications regarding the chrome rods states that "[c]ontouring of the metal implants should only be done with proper equipment" and that alterations should avoid "notching, scratching or reverse bending" when contouring, the Amended Complaint does not describe what constitutes proper equipment or reverse bending, nor whether any notching or scratching occurred. *Id.* ¶ 59. The Amended Complaint does assert that Dr. Hey "completely ignored" the manufacturer's instructions for correctly preparing and using the chrome rod and failed to inform the plaintiffs about the risks and benefits of the modified rod. *Id.* ¶ 60.

On June 25, 2011, Dr. Hey performed spinal surgery on Ms. Williams. *Id.* ¶ 65. Defendants Chewning and York, both Zimmer representatives, were present in the operating room during the surgery. *Id.* ¶ 68. As part of the surgery, Dr. Hey used Zimmer Clamps to affix the U-shaped chrome rod to Ms. Williams spine. *Id.* ¶ 66. The Zimmer Clamps did not receive FDA 510(k) clearance until six weeks after the June 25, 2011 surgery. *Id.* ¶ 67. According to his surgery notes, Dr. Hey spoke with an unnamed Zimmer representative, and that conversation confirmed his belief that the Zimmer Clamp would work well to hold the chrome rod in place.

Id. ¶ 70. Later, on his blog, Dr. Hey wrote that Defendants Chewning, York, and Dyer had promoted his use of the U-shaped rod and Zimmer Clamps. *Id.* ¶ 76.

After the procedure, Ms. Williams began to experience worse and worse pain. *Id.* ¶ 80. She visited several neurosurgeons and eventually received corrective revision surgery in September and October of 2013 to alleviate her pain. *Id.* ¶¶ 81-85, 96-97. Prior to the revision surgery, a neurosurgeon informed Ms. Williams that the U-shaped rod and Zimmer Clamps were the cause of her pain and that they should be removed. *Id.* ¶ 92.

The plaintiffs bring four claims against the defendants stemming from the defendants' representations and Dr. Hey's surgery. Count One asserts a claim of negligence *per se* for violations of FDA regulations. Count Two asserts a claim of negligent supervision of employees against Zimmer, Pioneer, and RTI Surgical for their employees' violations of the FDCA. Count Three asserts a claim of negligent failure to warn where Chewning, York, and Dyer failed to warn of the risk of off-label usage of the chrome rod, in violation of the FDCA. Count Four asserts a claim of ordinary negligence resulting from Chewning, York, and Dyer's promotion of off-label use of the chrome rod and FDA-unapproved use of the Zimmer Clamps. Counts Three and Four also assert the liability of Zimmer, Pioneer, and RTI Surgical under the doctrine of *respondeat superior*. The defendants have moved to dismiss. The plaintiffs have moved to remand this action to state court and to amend the Amended Complaint to add Dr. Hey as a defendant.

II. DISCUSSION

a. Motion to Remand

Federal courts have limited jurisdiction, whose bounds are demarcated by the Constitution and by statute. *See Gunn v. Minton*, 133 S. Ct. 1059, 1064 (2013). Per statute,

district courts "have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. Generally, cases arise under federal law where federal law creates the asserted cause of action. *Gunn*¸ 133 S. Ct. at 1064. However, a state law claim may also arise under federal law where the state claim (1) necessarily raises a federal issue, (2) that is actually disputed, (3) substantial, and (4) capable of resolution in federal court without disturbing the congressionally-approved federal-state judicial balance. *See id.* at 1065 (citing *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005)). Here, the plaintiffs' Amended Complaint meets the standard set forth in *Gunn* and *Grable*.

i. The Amended Complaint necessarily raises a federal issue.

"A plaintiff's right to relief for a given claim necessarily depends on a question of federal law only when *every* legal theory supporting the claim requires the resolution of a federal issue." *Dixon v. Coburg Dairy, Inc.*, 369 F.3d 811, 816 (4th Cir. 2004) (emphasis in original). Here, the Amended Complaint depends entirely on whether or not the defendants violated the FDCA and MDA. Indeed, the opening paragraphs state exactly that theory while the individual counts reiterate that recovery is premised on the defendants' violations of the FDCA and MDA. *See* Am. Compl. [DE-1-1] ¶¶ 1-2, 101-04, 109-10, 113, 116, 118-121, 126, 129. There is no alternative legal theory for recovery.

ii. The federal issue is actually disputed.

A federal issue is actually disputed where it is the "central point of dispute." *Gunn*, 133 S. Ct. at 1065. Here, the alleged violations of the FDCA and MDA are the central point of dispute. Without the alleged violations, the Amended Complaint would not raise a claim against the defendants.

iii. The federal issue is substantial.

The substantiality inquiry looks to "the importance of the issue to the federal system as a whole." *Id.* at 1066. This can mean the government's "direct interest in the availability of a federal forum to vindicate its own administrative action," *Grable*, 545 U.S. at 315, as well as whether the "'decision depends upon the determination' of 'the constitutional validity of an act of Congress which is directly drawn in question,'" *Gunn*, 133 S. Ct. at 1066 (quoting *Smith v. Kansas City Title & Tr. Co.*, 255 U.S. 180, 201 (1921)). Courts may also consider the precedential effect of allowing state courts to decide cases involving federal issues, *Gunn*, 133 S. Ct. at 1067, and whether a federal private right of action exists or not, *Grable*, 545 U.S. at 318.

Here, the substantiality inquiry weighs against remand. This case involves a substantial question of whether the FDCA preempts the plaintiffs' claims. *See* Motions to Dismiss [DE-27, -39]. Remand of this matter to state court would allow state courts to determine how the FDCA applies to the present facts and set national precedent. This case further involves the MDA, "which swept back some state obligations and imposed a regime of detailed federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). The regulations allegedly violated by the defendants are part of a regulatory scheme meant to peel back state involvement in favor of FDA oversight. This manifests the importance of the issue to the federal system as a whole. The federal issue is substantial.

iv. The federal issue can be resolved without disturbing the congressionally-approved federal-state judicial balance.

The MDA was passed by Congress to substitute comprehensive federal oversight of medical device regulation for what had previously been scattered state regulation. This case requires, at its heart, answering whether the defendants violated the FDCA by promoting the use of unapproved clamps and the off-label use of the chrome rods. That is the type of question the

MDA intended to move primarily under federal oversight. Certain variations on the question might be appropriate for state court resolution, such as where a violation of the FDCA "would traditionally give rise to liability under state law . . . even if the FDCA had never been enacted." *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009). However, this is not such a case. Resolving the FDCA question at the heart of this case will not upset the federal-state judicial balance as approved by Congress.

The Motion to Remand [DE-31] is DENIED. While the Amended Complaint asserts state law claims, it necessarily raises the federal issue of how the FDCA applies to the facts of this case. That issue is actually disputed, substantial, and capable of resolution before this court without disturbing the congressionally-approved federal-state judicial balance.

b. Motion to Dismiss Pursuant to Rule 12(b)(6)

i. Legal Standard

The purpose of a motion to dismiss under Rule 12(b)(6) is to test the legal sufficiency of the complaint, not to resolve conflicts of fact or to decide the merits of the action. *Edwards v. City of Goldsboro*, 178 F.3d 231, 243-44 (4th Cir. 1999). In considering a motion to dismiss, the court assumes the truth of all facts alleged in the complaint and the existence of any fact that can be proved, consistent with the complaint's allegations. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *E. Shore Mkts., Inc. v. J.D. Assocs. Ltd. P'ship*, 213 F.3d 175, 180 (4th Cir. 2000). However, the " '[f]actual allegations must be enough to raise a right to relief above the speculative level' and have 'enough facts to state a claim to relief that is plausible on its face.'" *Wahi v. Charleston Area Med. Ctr., Inc.*, 562 F.3d 599, 615 n.26 (4th Cir. 2009) (alteration in original) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007)). "[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and

conclusions, and a formulaic recitation of a cause of action's elements will not do." *Twombly*, 550 U.S. at 555 (second alteration in original). Moreover, a court "need not accept the legal conclusions drawn from the facts" nor "accept as true unwarranted inferences, unreasonable conclusions, or arguments." *E. Shore Mkts.*, 213 F.3d at 180.

ii. Conflict preemption bars the plaintiffs' claims.

Under the Supremacy Clause of the United States Constitution, federal law may preempt state law in one of three ways: (1) Congress may pass a statute that expressly preempts state law; (2) Congress may impliedly preempt state law by occupying an entire field of regulation; and (3) state law may conflict with federal law, either because "compliance with both state and federal law is impossible" or because the state law impedes a federal purpose. *Abbot by Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1111 (4th Cir. 1988). We deal here with the third class of preemption, particularly as it was analyzed and applied in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

In *Buckman*, the plaintiffs sued over the use of "orthopedic bone screws" that had been used during spinal surgery. *Id.* at 344. The plaintiffs alleged that the defendants had obtained FDA approval for the bone screws through fraud, which fraud they argued was a "but for" cause of their injuries. *Id.* The Supreme Court disagreed. The Court discussed the FDA's review processes, which it characterized as "comprehensive" and rigorous. *Id.* at 348. The Court further noted the FDA's various powers for enforcing the review processes and any violations of the applicable requirements. *Id.* at 349.

The Court ultimately held that the "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. The Court further reasoned, in part, that allowing state-law

claims for fraud-on-the-FDA could deter potential applicants from "seeking § 510(k) approval of devices with potentially beneficial off-label uses." *Id.* Because the plaintiffs' claims would have "exert[ed] an extraneous pull on the scheme established by Congress," the FDCA preempted those claims. *Id.* at 353.

Buckman did leave room for a small range of state-law claims based on the FDCA, namely those state-law claims that would rely on traditional state tort law independent of the FDCA. *See id.* at 352-53. Put in other terms, "a state law claim only endures if it manages to incorporate, but not depend entirely upon, an FDCA violation and is premised on conduct that would give rise to liability under traditional common law principles." *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 369 (E.D.N.Y. 2010) (internal quotation marks omitted). If, however, the defendant would not be liable "but for the FDCA, 'then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman*.'" *Id.* (quoting *Lefaivre v. KV Pharm. Co.*, No. 4:09CV00588SNLJ, 2010 WL 59125, at *3 (E.D. Mo. Jan. 5, 2010), *rev'd*, 636 F.3d 935 (8th Cir. 2011)).

The plaintiffs make four arguments as to why the preemption analysis of *Buckman* does not apply to the present case: (1) the holding of *Buckman* is limited to situations involving "fraud-on-the-FDA" claims; (2) the claims in the present case do not fall under the express preemption provided for in the MDA; (3) the off-label use in the instant case should not have been permitted; and (4) the plaintiffs' claims do not depend on FDA premarket approval, but upon off-label use of the chrome rods and failure to disclose lack of FDA approval for the clamps. *See* Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss [DE-45] at 3-6. All of these arguments fail.

1. The holding of *Buckman* applies to any state-law claim that depends entirely upon an FDCA violation and applies even to those claims based on off-label use and promotion and on failure to advise patients of a lack of FDA approval.

Under *Buckman*, a state law claim is not preempted by the FDCA (1) if it only incorporates but does not rely entirely upon an FDCA violation, and (2) if the claim is founded on conduct that would otherwise give rise to liability under state law. *See In re Bayer Corp.*, 701 F. Supp. 2d at 369. However, if the defendant would not be liable "but for" the alleged FDCA violations, "then the plaintiff is effectively suing for a violation of the FDCA" and the claim is preempted under *Buckman*. *Id.*

The *Buckman* Court's holding that the FDCA does not provide a private right of action is not limited to the facts of *Buckman*. "*Buckman* has been applied in particular contexts to impliedly preempt such state law claims as breach of warranty, negligence per se, design defect, and failure to warn." *Evans v. Rich*, No. 5:13-CV-868-BO, 2014 WL 2535221, at *2 (E.D.N.C. June 5, 2014) (citing *In re Medtronic*, 592 F. Supp. 2d 1147, 1159-64 (D. Minn. 2009)). Indeed, case law indicates that the *Buckman* Court's holding preempts claims brought based on a failure to disclose a lack of FDA approval and for promotion of off-label use. For example, the District Court for the Western District of Michigan held that there was no "traditional state-law duty to refrain from off-label promotion," meaning that the plaintiff's claim for that harm was preempted. *Wright v. Medtronic, Inc.*, No. 1:13-CV-716, 2015 WL 328596, at *9 (W.D. Mich. Jan. 23, 2015). The court held likewise for the plaintiff's claim of negligence based on the defendant's promotion of off-label use of a bone-grafting device. *Id.* at *11.

The Ninth Circuit has further held that the FDCA can preempt even those claims based on a failure to disclose a lack of FDA approval. *See Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1119-20 (9th Cir. 2013). The *Perez* court, as in *Buckman*, highlighted the FDA's role in

investigating and enforcing potential FDCA violations, as well as citizens' limited ability to petition the FDA to take administrative action. *Id.* at 1119. Similarly, the District Court for the District of Minnesota held that plaintiffs cannot recover for state-law claims that depend on a failure to obtain FDA approval. *See Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1138, 1151 (D. Minn. 2011). In *Kapps*, the plaintiff sued over the use of a catheter that had not received FDA approval prior to use during the plaintiff's heart surgery. *See id.* Despite that fact, the court held that the plaintiff could not recover for the lack of FDA approval alone. *Id.* at 1151. Citing *Buckman*, the court held that "a private litigant may not sue a medical-device manufacturer for violating the FDCA." *Id.* The court then entered summary judgment on behalf of the device manufacturer on claims of negligence *per se* and negligent failure-to-warn. *Id.* at 1151-53. The court finds the logic of these cases compelling and adopts that logic as its own.

The plaintiffs in the present case have brought claims for (1) negligence *per se*, (2) negligent supervision of employees, (3) negligent failure to warn, and (4) negligence, all of which are premised on either off-label use of the chrome rods or failure to advise that the clamps had not yet received FDA approval. The FDCA preempts these claims. *Buckman* is not limited to fraud-on-the-FDA claims. Instead, it applies to any claims that depend entirely upon alleged FDCA violations, including (1) claims of off-label use and promotion of a medical device, allegedly in violation of the FDCA, and (2) claims that a plaintiff was not advised that a device had not yet obtained FDA approval. The present claims depend entirely upon alleged violations of the FDCA. *Buckman* applies. This disposes of the plaintiffs' first, third, and fourth arguments.

2. An express preemption provision does not preclude application of conflict preemption.

Buckman dispensed with the notion that an express preemption provision prevents the application of conflict preemption. 531 U.S. at 352. ("[N]either an express pre-emption provision

nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'" (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000))). This disposes of the plaintiffs' second argument.

The Motions to Dismiss [DE-27, -39, -54] are ALLOWED. The plaintiffs have made no showing that their claims are predicated on anything other than violations of the FDCA. Therefore, the FDCA preempts their claims. Even if the plaintiffs could establish their claims based solely on FDCA violations, the court doubts that the Amended Complaint's allegations are sufficient to state a claim as to the chrome rods, although the court does not reach that question. The plaintiffs' Amended Complaint [DE-1-1] is DISMISSED WITH PREJUDICE.[2]

c. Motion to Add Party Defendant

The plaintiffs have moved to add Lloyd Albert Hey, M.D., as a party to this action. *See* Motion to Add Party Defendant [DE-43]. However, because the court has dismissed the plaintiffs' Amended Complaint, and because adding Dr. Hey would not change that outcome, the Motion to Add Party Defendant [DE-43] and the motions to file supplemental briefings [DE-50, -53] are DISMISSED AS MOOT.

III. CONCLUSION

For the foregoing reasons, the Motion to Remand [DE-31] is DENIED; the Motions to Dismiss [DE-27, -39, -54] are ALLOWED; the Motion to Add Party Defendant [DE-43] and the motions to file supplemental briefings [DE-50, -53] are DISMISSED AS MOOT. The plaintiffs' Amended Complaint [DE-1-1] is DISMISSED WITH PREJUDICE. The Clerk of Court is DIRECTED to close this case.

[2] The court finds that any amendment to the complaint would be futile. Therefore, dismissal with prejudice is warranted. *See McLean v. United States*, 566 F.3d 391, 400 (4th Cir. 2009).

SO ORDERED.

This, the 14th day of July, 2015.

James C. Fox

JAMES C. FOX
Senior United States District Judge